K110450

Section 5 – 510(k) Summary

MAY 1 0 2011

Submitter:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 3005188751
Contact Person:	Wendy Pinor Sr. Regulatory Affairs Specialist Phone (651) 756-5223 Fax (952) 930-9481
Date Prepared:	February 15, 2011
Common Name:	Catheter Introducer
Trade Name:	82cm Agilis NxT™ Steerable Introducer
Classification:	Class II - 21 CFR 870.1340 Catheter Introducer
Panel:	Cardiovascular
Product Code:	DYB
Predicate Device(s):	Agilis NxT Steerable Introducer (K081645, K061363)

Device Description

The Agilis NxT Steerable Introducer consists of a steerable sheath, dilator and guidewire, which is indicated for introducing various cardiovascular catheters into the heart via the venous anatomy, including the left side of the heart through the interatrial septum. It is an 8.5F asymmetrical bi-directional steerable introducer with a large curl at the distal tip and a useable length of 82 cm. The proximal end of the device sheath is fitted with a hemostasis valve to minimize blood loss during catheter insertion and/or exchange over a guidewire. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The handle is equipped with a rotating collar to deflect the large curl 90° in the counterclockwise direction and 180° in the clockwise direction. The sheath is filled with radiopaque material for visualization under fluoroscopy.

A dilator and guidewire are packaged with the introducer and are designed to facilitate the introduction and passage of the introducer through the vasculature.

Comparison to Predicate Devices

The Agilis™ NxT Steerable Introducer has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the Agilis™ NxT Steerable Introducer are substantially equivalent to the predicate device

including packaging, biocompatibility, sterilization, and labeling. Where dimensional differences exist between the subject device and the predicate device, performance testing demonstrates that these differences do not adversely affect safety and effectiveness. The introducer acts as a functioning guide/platform for introduction of other diagnostic and therapeutic devices.

Intended Use

The 82cm Agilis NxT™ Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart via the venous anatomy, including the left side of the interatrial septum.

Testing

Bench Testing

The Use and Design FMEAs were used in evaluating the need for performance and design verification testing due to the modifications made to the predicate Agilis NxT device. Testing performed demonstrates that the device meets all product specifications and performance requirements.

Test	*Result*
Surface Visual Standard	Pass
Usable Shaft Length	Pass
Curve Angle	Pass
Deflection Durability	Pass
Shaft Kink	Pass
Curve Retention	Pass
Shaft Torque Test	Pass
Tip Tensile	Pass
Sheath/Dilator	Pass

Test	*Result*
Distal tip inner diameter	Pass
Insertion Forces	Pass
Radiopacity	Pass
3-way Stopcock	Pass
Shaft to Hub Tensile	Pass
Stopcock to Hub bond	Pass
Freedom from Leaks	Pass
Luer Taper	Pass
Lure Stress Cracking	Pass

Sterilization

Based on results of EtO residual, lethality, natural product sterility, bacteriostasis and fungistasis testing, bioburden and LAL testing, it has been determined that the 82 cm Agilis NxT Steerable Introducer meets all applicable specifications.

Test	*Result*	*Test*	*Result*
LAL	Pass	ECH Residual	Pass
Bioburden	Pass	Lethality	Pass
EtO Residual	Pass		

Packaging:

Sterile barrier package testing meets specifications and performance requirements throughout the lifetime of the product, as labeled.

The following package testing was performed

- Performance Testing of Shipping Containers (ASTM D4169-05)
- Visual Inspection (ASTM F1886-98)
- Seal Strength (ASTM F88-00)
- Bubble Leak (ASTM F2096-04)

There were no failures reported for any of the tests. The testing demonstrates that the Agilis NxT packaging will maintain its integrity and provide a sufficient barrier to ensure the sterile barrier will not be breached.

Product shelf life testing demonstrates that the device meets product specifications and performance requirements throughout the lifetime of the product, as labeled.

Biocompatibility

Testing demonstrates that the device is biocompatible.

Biological Test	***Results***
Cytotoxicity	Pass
Sensitization	Pass
Intracutaneous Reactivity (Irritation)	Pass
Systemic Toxicity (acute, includes pyrogenicity)	Pass
Chemical Characterization / Gas Chromatography with Mass Spectrometry	Pass
Chemical Characterization / Inductively Coupled Plasma (ICP)	Pass
Partial Thromboplastin Time – PTT	Pass

Biological Test	***Results***
Pyrogenicity	Pass
Hemocompatibility – Hemolysis	Pass
Hemocompatibility- Complement Activation System	Pass
Hemocompatibility – Thrombosis	Pass
Chemical Characterization / Fourier Transdorm Infrared Spectroscopy (FTIR)	Pass
Chemical Characterization / Physicochemical Non-volatile Residue (NVR)	Pass

Pre-Clinical and Clinical Testing

No animal or human testing was conducted on the 82 cm Agilis NxT Introducer.

Testing of the 82 cm Agilis NxT Steerable demonstrates that the 82 cm Agilis NxT Steerable Introducer design meets product specifications and intended use.

Conclusion

St. Jude Medical considers the 82 cm Agilis NxT Steerable Introducer to be equivalent to or substantially similar to the predicate device listed above. This conclusion is based upon the devices' similarities in design, technological characteristics, principles of operation, materials, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUN 15 2015

St. Jude Medical
c/o Ms. Wendy Pinor
Sr. Regulatory Affairs Specialist
14901 Deveau Place
Minnetonka, MN 55345

Re: K110450
Trade/Device Name: 82cm Agilis NxT™ Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 15, 2011
Received: February 16, 2011

Dear Ms. Pinor:

This letter corrects our substantially equivalent letter of May 10, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K110450

Device Name:

82cm Agilis NxT™ Steerable Introducer

Indications for Use:

The 82cm Agilis NxT™ Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart via the venous anatomy, including the left side of the heart through the interatrial septum

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110450